2025 Early Career Scholar Program

An Intensive Multi-day Opioid REMS Initiative in Pain Management

CME OUTFITTERS

This activity is supported by an independent educational grant from the Opioid Analgesic REMS Program Companies.

Please see https://www.opioidanalgesicrems.com/Resources/Docs/List_of_RPC_Companies.pdf for a listing of REMS Program Companies. This activity is intended to be fully compliant with the Opioid Analgesic REMS education requirements issued by the U.S. Food and Drug Administration (FDA).

CDC Guidelines for Opioid Prescribing and REMS Blueprint Overview

Carrie Hyde, MD

Internal Medicine/Hospice & Palliative Medicine

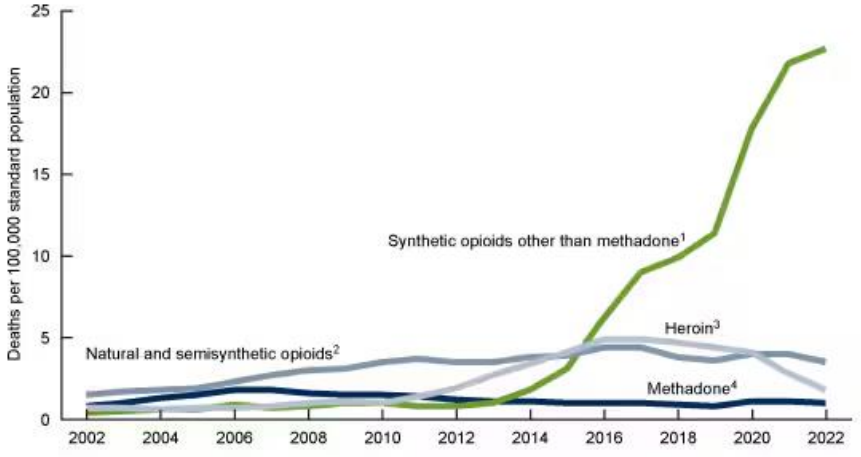
Learning Objectives

- Incorporate strategies from the 2022 CDC Guideline for Prescribing Opioids into the development of safe and effective pain management plans for patients with acute, subacute, and chronic pain

The Opioid Epidemic: Context and Rationale

Statistics

- Opioid overdose deaths:
  - In 2021, approximately **80,000 overdose deaths** in the United States involved opioids
  - Synthetic opioids (primarily fentanyl) were involved in over **88% of opioid-related deaths**
- Prescription opioids contribution:
  - From 1999 to 2022, over **700,000 people died from opioid overdoses**, including prescription opioids, heroin, and synthetic opioids
  - **8.6 million people** misused prescription opioids in 2022
- Economic impact:
  - The total economic cost of the opioid epidemic exceeds **$1 trillion annually**, including health care, lost productivity, and criminal justice expenses

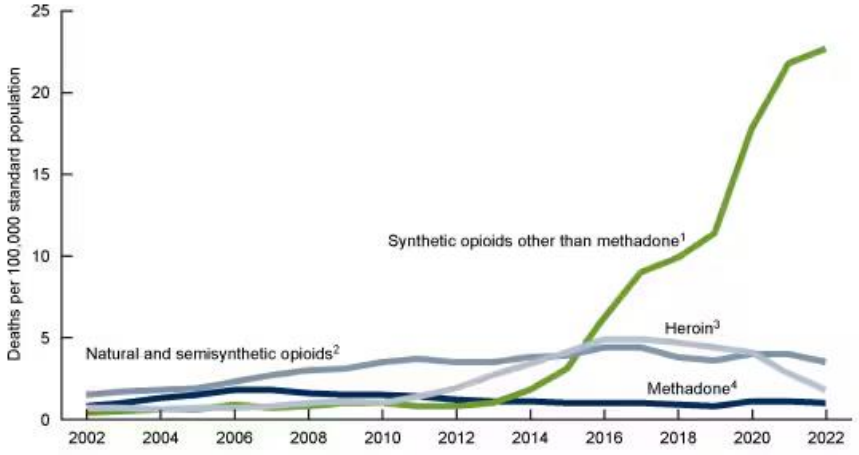


Centers for Disease Control and Prevention [CDC]. 2022. https://www.cdc.gov/nchs/pressroom/nchs_press_releases/2022/202205.htm. CDC. 2024. https://www.cdc.gov/overdose-prevention/about/understanding-the-opioid-overdose-epidemic.html. Substance Abuse and Mental Health Services Administration [SAMHSA]. 2024. https://www.samhsa.gov/data/report/2023-nsduh-annual-national-report. U.S. Joint Economic Committee. 2022. https://www.jec.senate.gov/public/index.cfm/democrats/2022/9/the-economic-toll-of-the-opioid-crisis-reached-nearly-1-5-trillion-in-2020.

The Opioid Epidemic: Context and Rationale

Historical Perspective

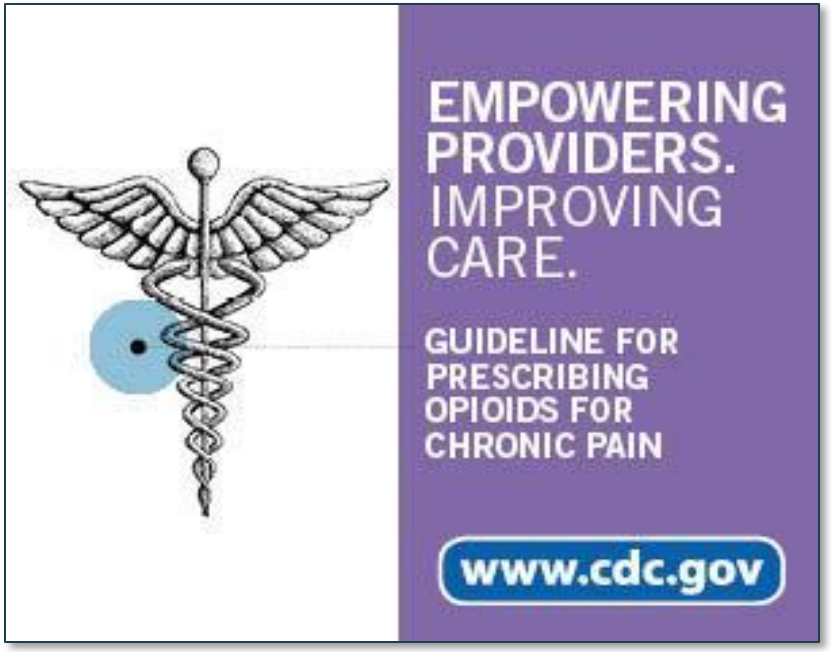
- 1990s
  - Pain as the fifth vital sign
  - Aggressive marketing by pharmaceutical companies led to a rise in opioid prescribing
- Initial 2016 CDC guidelines
  - Introduced due to a sharp rise in opioid-related deaths
  - Emphasized dosage thresholds (e.g., < 90 MME/day) leading to unintended consequences such as abrupt tapering and patient abandonment
- The need for updated guidelines in 2022
  - Recognition of unintended harm due to rigid 2016 guidelines
  - Shift toward risk mitigation and individualized patient care
  - Includes acute and subacute pain

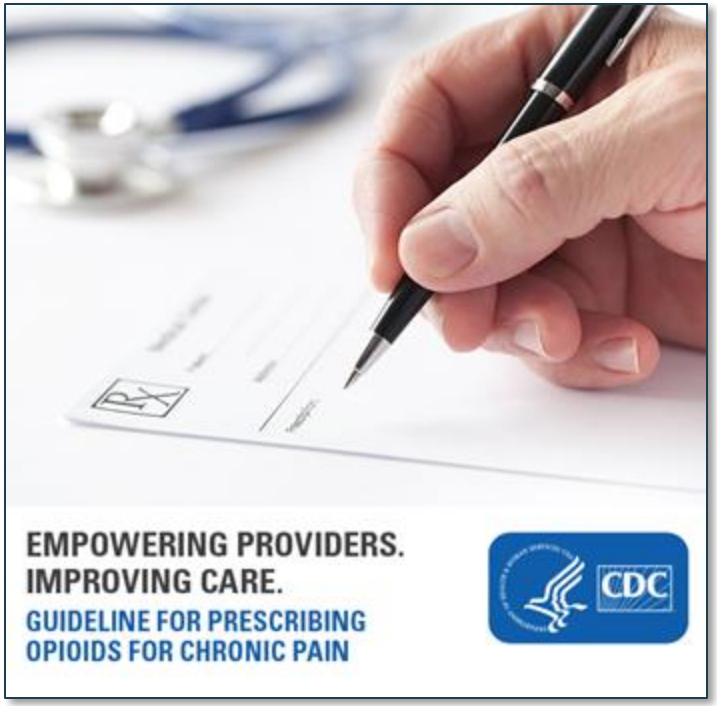


MME = morphine milligram equivalents.

Max MB, et al. *JAMA*. 1995;274(23):1874-1880. Dowell D, et al. *MMWR Recomm Rep*. 2016;65(1):1-49. Dowell D, et al. *MMWR Recomm Rep*. 2022;71(3):1-95.

The CDC 2016 vs 2022 High-Level Guideline Overview





Audience Poll

Have you changed your practice since release of the 2022 CDC's Clinical Practice Guideline for Prescribing Opioids for Pain?

A. Yes, I have made significant changes
B. Yes, but I still need to do more
C. No, I have not made any significant changes
D. No, I am unclear on the difference from the 2016 guidelines

CDC Guidelines 2016	CDC Guidelines 2022
Opioids are not first-line therapy for chronic pain, and if used should include non-opioid therapy in conjunction	Use non-opioids for first-line therapy
Establish goals for pain and function	Establish goals for pain and function
Discuss risks and benefits of opioid therapy	Discuss risks and benefits of opioid therapy
Use IR formulations when starting	Use IR formulations when starting
“Start low and go slow”	Use the lowest effective dose; **avoid increasing dosage to > 90 MME**
For acute pain, rarely > 7 days needed	Prescribe short durations for acute pain (3-7 days)
Reassess pain and function when doses **reach > 50 MME and avoid increasing > 90 MME**	Evaluate benefit and harm frequently
Evaluate patients for risk factors: SUD, depression, concurrent benzodiazepine use, and high dose of opioids	Use strategies to mitigate risk (naloxone, caution with benzodiazepines)
Check PDMP database	Review PDMP data regularly and at initiation
Annual urine drug testing	Use urine drug testing
Avoid prescribing concurrent benzodiazepines when possible	Avoid concurrent opioid and benzodiazepine prescribing
Offer MAT for those with OUD	Offer treatment for OUD

IR = immediate release; MAT = medication-assisted treatment; OUD = opioid use disorder; PDMP = prescription drug monitoring program; SUD = substance use disorder.

Dowell D, et al. *MMWR Recomm Rep.* 2016;65(1):1-49. Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95.

CDC 2022 Guidelines

- Key updates:
  - Removal of rigid dosing thresholds
  - Emphasis on shared decision-making (SDM) and individualized care
  - Expanded focus on acute, subacute, and chronic pain

Dowell D, et al. *MMWR Recomm Rep.* 2016;65(1):1-49. Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95.

CDC 2022 Guidelines

1 Opioids are not first-line therapy

- Non-pharmacologic and non-opioid pharmacologic therapy is preferred when treating chronic pain; opioids should only be prescribed if the benefits outweigh the risks
- If opioid are used, they should be used with other treatments such as NSAIDs, PT, CBT, and interventions

CBT = cognitive behavioral therapy; NSAIDs = non-steroidal anti-inflammatory drugs; PT = physical therapy.

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95.
U.S. Food and Drug Administration [FDA]. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

2 Establish goals for pain and function

- Set realistic treatment goals for patients who are prescribed opioids
- Treatment should be continued only if there is meaningful improvement in pain **and** function that outweighs the risks

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

3 Discuss risks and benefits

- Be aware of the different formulations and their classes to effectively prescribe and discuss risks and benefits

Class	Examples	Uses	Safety Concerns
Natural opiates	Morphine, Codeine	Moderate to severe pain	Risk of respiratory depression, dependence, and sedation
Semisynthetic opioids	Oxycodone, Hydrocodone, Hydromorphone, Oxymorphone	Moderate to severe pain	High potential for abuse and overdose, constipation, drowsiness
Synthetic opioids	Fentanyl, Methadone, Tramadol, Meperidine	Severe pain, chronic pain, anesthesia	Fentanyl is highly potent, increased overdose risk; Methadone has cardiac risks
Mixed agonist-antagonists	Buprenorphine, Butorphanol, Nalbuphine, Pentazocine	Pain management, opioid dependence	Ceiling effect reduces overdose risk but may cause withdrawal in dependent patients
Opioid antagonists	Naloxone, Naltrexone	Opioid overdose reversal, dependency treatment	Can precipitate withdrawal symptoms in opioid-dependent individuals

FDA. 2021. https://www.fda.gov/drugs/information-drug-class/opioid-medications. Opioid Analgesic REMS. 2025. https://www.opioidanalgesicrems.com/products.html.
Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.
Naloxone [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.
Naltrexone [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/208271s000lbl.pdf.

CDC 2022 Guidelines

3 Discuss risks and benefits

- Be explicit and realistic in telling patients that complete pain relief is unlikely and that there is no good evidence that long-term opioid use improves pain or function
- All risks should be discussed, including the most serious risks such as fatal respiratory depression and OUD

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines: Patient Counseling

- Importance of adherence to prescribed dosing regimen
- Patients should use the least amount of medication necessary to treat pain and for the shortest amount of time
- The risk of serious adverse events that can lead to death
- The risk of addiction that can occur even when product is used as recommended
- Known risk factors for serious adverse events, including signs and symptoms of overdose and opioid-induced respiratory depression, gastrointestinal obstruction, and allergic reactions, among others
- The most common side effects, along with the risk of falls, working with heavy machinery, and driving
- When to call the prescriber (e.g., managing adverse events, ongoing pain)
- How to handle missed doses
- The importance of full disclosure of all medications and supplements to all health care professionals (HCPs) and the risks associated with the use of alcohol and other opioids/benzodiazepines
- Product-specific concerns (such as not to crush or chew ER products, transdermal systems and buccal films should not be cut, torn, or damaged before use, etc.)
- How to safely taper dose to avoid withdrawal symptoms
- Safe storage and disposal (e.g., in-home disposal systems, kiosks, take back programs, mail back envelopes), risks of accidental exposure, and risks of diversion by family members and household visitors
- Never share any opioid analgesic with another person
- How and when to use naloxone products and their various means of administration
- Seeking emergency medical treatment if an opioid overdose occurs
- How to report adverse events and medication errors to the FDA

ER = extended release.

Opioid Analgesic REMS. https://www.opioidanalgesicrems.com/Resources/Docs/patient_counseling_document.pdf.
FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

3 Discuss risks and benefits

- The patient counseling guide covers most of the recommended patient counseling

Opioid Analgesic REMS **Patient Counseling Guide**

What You Need to Know About Opioid Pain Medicines

This guide is for you! Keep this guide and the Medication Guide that comes with your medicine so you can better understand what you need to know about your opioid pain medicine. Go over this information with your healthcare provider. Then, ask your healthcare provider about anything that you do not understand.

What are opioids?

Opioids are strong prescription medicines that are used to manage severe pain.

What are the serious risks of using opioids?

- Opioids have serious risks of addiction and overdose.
- **Too much opioid medicine in your body can cause your breathing to stop – which could lead to death.** This risk is greater for people taking other medicines that make you feel sleepy or people with sleep apnea.
- **Addiction** is when you crave drugs (like opioid pain medicines) because they make you feel good in some way. You keep taking the drug even though you know it is not a good idea and bad things are happening to you. Addiction is a brain disease that may require ongoing treatment.

Risk Factors for Opioid Abuse:

- You have:
  - a history of addiction
  - a family history of addiction
- You take medicines to treat mental health problems
- You are under the age of 65 (although anyone can abuse opioid medicines)

- Take your opioid medicine exactly as prescribed.
- Do not cut, break, chew, crush, or dissolve your medicine. If you cannot swallow your medicine whole, talk to your healthcare provider.
- When your healthcare provider gives you the prescription, ask:
  - How long should I take it?
  - What should I do if I need to taper off the opioid medicine (slowly take less medicine)?
- Call your healthcare provider if the opioid medicine is not controlling your pain. Do not increase the dose on your own.
- Do not share or give your opioid medicine to anyone else. Your healthcare provider selected this opioid and the dose just for you. A dose that is okay for you could cause an overdose and death for someone else. Also, it is against the law.
- Store your opioid medicine in a safe place where it cannot be reached by children or stolen by family or visitors to your home. Many teenagers like to experiment with pain medicines. Use a lock- box to keep your opioid medicine safe. Keep track of the amount of medicine you have.

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95.
Opioid Analgesic REMS. https://www.opioidanalgesicrems.com/Resources/Docs/patient_counseling_document.pdf.

CDC 2022 Guidelines

5 Consider the lowest effective dose

- The CDC recommends starting an opioid prescription with the lowest effective dose
- Evaluate risks and benefits if the dosage is greater than 50 MME/day and avoid dosages greater than 90 MME/day without justification
  - Protip: **document** your reasoning for your dosage and be able to calculate MME when you prescribe

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

4 Use IR formulations initially

- The CDC recommends initiating opioid treatment with IR prescriptions as opposed to ER
- Evidence shows that there is a higher chance of overdose if patients are started on long-acting opioids

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines: Consider The Lowest Effective Dose

- Be able to calculate MME when you prescribe
- Calculators and conversion tables vary
- The National Institutes of Health (NIH) Helping to End Addiction Long-term (HEAL) initiative made a standardized conversion table and calculator
  - Comprehensive comparison of opioid conversion factors across three key reference sources
  - Conversion ratios represent the multiplication factor used to convert a given opioid dose to its morphine equivalent
  - Dashes (−) indicate that the specific formulation was not included in that guideline

Medication	CDC 2016 Conversion Ratio	CDC 2022 Conversion Ratio	NIH HEAL 2024 Conversion Ratio
Buprenorphine tablet/film (mg) sublingual	30	—	38.8
Buprenorphine buccal film (mcg) buccal	0.03	—	0.039
Buprenorphine patch (mcg/hr) transdermal	12.6	—	2.2
Butorphanol (mg)	7	—	7
Codeine (mg)	0.15	0.15	0.15
Dihydrocodeine (mg)	0.25	—	0.25
Fentanyl buccal (mcg)	0.13	—	0.13
Fentanyl oral lozenge (mcg)	0.13	—	0.18
Fentanyl nasal (mcg)	0.16	—	0.16
Fentanyl patch (mcg/hr)	7.2	2.4	2.4
Hydrocodone (mg)	1	1	1
Hydrocodone LA (mg)	—	—	1
Hydromorphone (mg)	4	5	5
Hydromorphone (mg) LA	—	—	5
Levorphanol tartrate (mg)	11	—	11
Meperidine HCL (mg)	0.1	—	0.1
Methadone (mg)	Varies by dose (4 to 12)	4.7	4.7
Morphine (mg)	1	1	1
Morphine (mg) LA	—	—	1
Opium (mg)	1	—	1
Oxycodone (mg)	1.5	1.5	1.5
Oxycodone (mg) LA	—	—	1.5
Oxymorphone (mg)	3	3	3
Oxymorphone (mg) LA	—	—	3
Pentazocine (mg)	0.37	—	0.37
Tapentadol (mg)	0.4	0.4	0.3
Tapentadol (mg) LA	—	—	0.3
Tramadol (mg)	0.1	0.2	0.2
Tramadol (mg) LA	—	—	0.2

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.
Adams MCB, et al. *Pain*. 2025 Feb 3. [Epub ahead of print].

Morphine Milligram Equivalent Doses for Commonly Prescribed Opioids

Opioid	Conversion Factor
Codeine	0.15
Fentanyl transdermal (in mcg/hr)	2.4
Hydrocodone	1.0
Hydromorphone	5.0
Methadone	4.7 ★
Morphine	1.0 ★
Oxycodone	1.5
Oxymorphone	3.0
Tapentadol	0.4 ★
Tramadol	0.2

★ = Special caution recommended when converting hydromorphone, methadone, and tapentadol

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

Quick Exercise

- Calculate the following MME:
  - Patient on (easy):
    - Oxycodone 10 mg q6h PRN
    - Takes 3-4 doses per day

- Steps:

1. Total daily dose of opioid (in mg)
2. Convert to morphine equivalent
   - Multiply by the conversion factor
3. Add together all the doses once converted to morphine equivalent

Dowell D, et al. *MMWR Recomm Rep*. 2022;71(3):1-95.

Quick Exercise

- Calculate the following MME:
  - Patient on (medium):
    - Morphine sulfate CR 30 mg TID
    - Oxycodone 20 mg q6h PRN
      - Takes 2 oxycodone per day but prescribed enough to take 3/day

- Steps:

1. Total daily dose of opioid (in mg)
2. Convert to morphine equivalent
   - Multiply by the conversion factor
3. Add together all the doses once converted to morphine equivalent

CR = controlled release.

Dowell D, et al. *MMWR Recomm Rep*. 2022;71(3):1-95.

CDC 2022 Guidelines

6 Prescribe short durations for acute pain

- Because long-term opioid use often starts with treatment for acute pain, recommend prescribing
  - The lowest effective dose
  - Immediate-release formulations
  - Only the quantity needed to the expected duration of the pain

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. Scully RE, et al. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

6 Prescribe short durations for acute pain

- Per *JAMA Surgery*, median prescription lengths for opioids after common surgical procedures are as follows:
  - **4 days** for appendectomy and cholecystectomy
  - **5 days** for inguinal hernia repair and mastectomy
  - **4 days** for hysterectomy
  - **5 days** for anterior cruciate ligament repair and rotator cuff repair
  - **7 days** for discectomy
- Taper opioid by 6 weeks after most major surgeries, with dose reductions by 20% weekly if there are no improvements in function and pain

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. Scully RE, et al. *JAMA Surg*. 2018;153(1):37-43. Wu CL, et al. *Anesth Analg.* 2019;129(2):567-577. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

7 Evaluate benefits and risks frequently

- Evaluate within 1 to 4 weeks of starting opioid treatment
- Re-evaluate these risk and benefits every 3 months at minimum
- If the benefits fail to outweigh the risks, the CDC suggests introducing other therapies and tapering the opioids to a lower dose or until they are discontinued
- Again, **document** your reasoning for continuing or the tapering plan

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

8 Mitigate risk

- Opioid management should include mitigation of risks, offering naloxone when there is an increased risk of overdose
  - Patient with history of overdose
  - Patient with history of substance abuse
  - Opioid dosages over 50 MME/day
  - Concurrent benzodiazepine use

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

9 Review PDMP data

- Physicians should review patient's PDMP data
  - Are they adherent to the regimen set forth?
  - Are they filling prescriptions from another provider?
  - Does this align with pill counts in clinic?
- This should be checked when starting **any** controlled substance and at least every 3 months while still prescribing

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

10 Use urine drug testing

- Consider testing the patient's urine for opioids before initiating a treatment plan using opioids
- Test (at least) annually while still prescribing opioids
- Protip: know how to read UDS and when to get confirmatory testing
  - Cocaine is always cocaine; amphetamines, PCP, barbiturates need confirmatory tests
  - Synthetic opioids such as oxycodone, hydrocodone

PCP = phencyclidine; UDS = urine drug screen.

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

Substance (Tested Metabolite)	Detection Start	Detection End	False Positives	False Negatives
Amphetamines (-amphetamine)	4-6h	2-3d	Pseudoephedrine, phenylephrine, amantadine, atomoxetine, bupropion, chloroquine, metformin, ranitidine, chlorpromazine, trazodone, promethazine, hemp-containing foods, proton pump inhibitors	MDA, MDMA
Benzodiazepines (oxazepam)	2-7h	Most 3-5d Diazepam 10-30d	Coca tea, some forms of yerba mate, sertraline	Clonazepam, lorazepam, alprazolam, midazolam,
Phencyclidine	4-6h	7-14d	Dextromethorphan, venlafaxine, ibuprofen, thioridazine, diphenhydramine, tramadol, ketamine, lamotrigine, zolpidem	None
Opiates (morphine)	2-6h	1-3d	Levofloxacin, ofloxacin, imipramine, naltrexone, rifampin, dextromethorphan	Oxycodone, hydrocodone, tramadol, methadone, buprenorphine - synthetic opioids
Cocaine (benzoylecgonine)	2-6h	12h, possibly 2-4d	Coca leaves in tea drinks	None
Cannabinoids (11-carboxy-delta9-tetrahydrocannabinol)	1-3h	3-30d depending on chronicity of use	Promethazine, NSAIDs, pantoprazole	Synthetic/designer cannabinoids
Tricyclics	8-12h	2-7d	Cyclobenzaprine, quetiapine, carbamazepine, cyproheptadine, hydroxyzine, cetirizine, diphenhydramine	None
Barbiturates	2-4h	Short-acting up to 24h, long-acting up to 3 weeks	Ibuprofen, naproxen	Sodium thiopental

MDA = 3,4-methylenedioxyamphetamine; MDMA = 3,4-methylenedioxymethamphetamine.

SAMHSA. 2021. https://www.ncbi.nlm.nih.gov/books/NBK574915/table/p5.t2/. SAMHSA. 2012. https://library.samhsa.gov/sites/default/files/sma12-4668.pdf.
Kale N. *Am Fam Physician.* 2019;99(1):33-39. LabCorp. 2016. https://www.labcorp.com/content/dam/labcorp/files/orgs-hhs-mc-launch/L1123-0216-5.pdf.

CDC 2022 Guidelines

11 Avoid concurrent benzodiazepine use

- Whenever possible!

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

CDC 2022 Guidelines

12 Offer treatment for opioid use disorder

- Offer or arrange treatment for a patient if they develop OUD
- Find SUD Treatment | SAMHSA


SAMHSA
Substance Abuse and Mental Health Services Administration

Opioid Treatment Program Directory

Select to view the opioid treatment programs in a State

Arizona

Opioid treatment programs in Arizona: 74

Download (Excel document)

Program Name	Street	City	State	Zip Code	Phone	Certification	First Full Certification Date/CMS Use

Dowell D, et al. *MMWR Recomm Rep.* 2022;71(3):1-95. SAMHSA. https://dpt2.samhsa.gov/treatment/. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

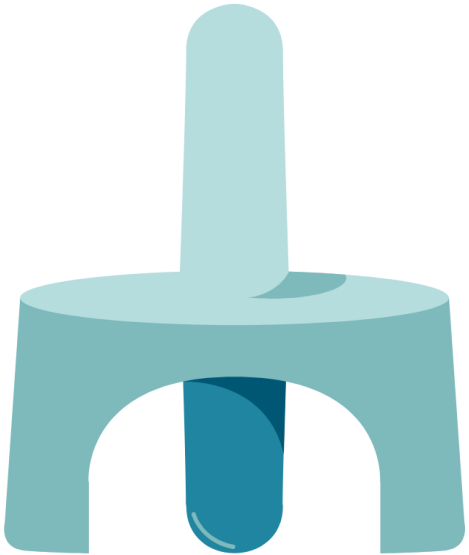
CDC 2022 Guidelines: Clinical Pearls

- When to consider opioids for pain management
- Dosage optimization strategies
- Frequency and timing of follow-ups

Wu CL, et al. *Anesth Analg.* 2019;129(2):567-577.

CDC 2022 Guidelines: Risk Mitigation

- Co-prescribing naloxone
- Risk stratification for OUD
- Patient education and informed consent



Dowell D, et al. *MMWR Recomm Rep.* 2016;65(1):1-49. Califf RM, et al. *N Engl J Med.* 2016;374(15):1480-1485. FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

Patient Case: Mr. J

54-year-old man with chronic low back pain radiating to the right leg, consistent with lumbar radiculopathy

Fell at work 10 months ago; pain is 7/10, worse with standing or walking and partially relieved with sitting

Reduced mobility and difficulty sleeping, with impact on his ability to work or engage in daily activities

Patient history: well-controlled diabetes mellitus II, hypertension, no history of SUD or psychiatric illness

Currently on metformin, lisinopril, NSAIDs (limited relief), and PT, which he discontinued after 3 weeks of no improvement

Next Steps?

- **Pain assessment**
  - Documented as moderate to severe and affecting function

Next Steps?

- **Pain assessment**
  - Documented as moderate to severe and affecting function
- **Risk assessment**
  - Conducted an ORT, low risk for opioid misuse
  - Reviewed the PDMP, no concerning patterns

ORT = opioid risk tool.

Next Steps?

- **Pain assessment**
  - Documented as moderate to severe and affecting function
- **Risk assessment**
  - Conducted an ORT, low risk for opioid misuse
  - Reviewed the PDMP, no concerning patterns
- **Patient goals**
  - Improve mobility and quality of life, focus on returning to work

What Are Your First-Line Choices at This Visit?

- Restart PT, emphasizing core strengthening and stretching
- Prescribe gabapentin for neuropathic pain
- Encourage NSAID use with gastroprotective agent

Patient Case: Mr. J

Four-week follow-up visit:

Mr. J has had minimal improvement and says he is frustrated. He has adhered to the plan yet is still having significant impairment in daily activities.

What are your next steps?

Next Steps?

- You discuss risks and benefits, and through SDM decide on a trial of oxycodone 5 mg q8H PRN
- Provide informed consent on potential side effects and importance of adherence

PRN = as needed; q8H = every 8 hours.

Next Steps?

- You discuss risks and benefits and through SDM decide on a trial of oxycodone 5 mg q8H PRN
- Provide informed consent on potential side effects and importance of adherence
- What risk mitigation strategies do you use?
- MME calc?
- Naloxone prescribed and explained
- PDMP, UDS

Audience Poll

When should you see him again?

A. 2 weeks
B. 4 weeks
C. 8 weeks
D. 12 weeks

Follow-Up Visit

- You see him in 2 weeks and he reports a pain reduction to 4/10, improvement in pain and somewhat in function
- You decide to continue for 2 more weeks and place a referral to pain specialist
- Ensure that you have discussed tapering opioids as long-term plans are put in place to begin functionality
- Regular monitoring to prevent long-term dependence

Opioid REMS Blueprint Overview

- What is opioid REMS?
  - Risk Evaluation and Mitigation Strategy: a program mandated by the FDA to ensure that the benefits of certain medications outweigh their risk
  - Formerly FDA Blueprint
- Opioids
  - High potential for misuse, abuse, addiction, and overdose
  - Aims to educate prescribers and patients and mitigate risk associated with opioid use

FDA. 2022. https://www.fda.gov/drugs/information-drug-class/historical-information-rems-opioid-analgesics.
FDA. 2024. https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.
FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

REMS Blueprint Overview

- Scope: covers both outpatient and inpatient opioid prescribing
- Education requirements:
  - Prescribers must complete REMS-compliant education on opioid prescribing; fulfills MATE (Medication Access and Training Expansion Act) requirements
    - New or renewing DEA registrants have completed at least 8 hours of training on opioids or other SUD as well as safe pharmacological management of dental pain
  - Dosage calculations, risk assessment, and tapering strategies

DEA = Drug Enforcement Agency.

FDA. 2024. https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.
FDA. 2023. https://www.fda.gov/media/173774/download?attachment.

REMS Blueprint Overview

1. Prescriber Education

- Program mandates manufacturers of ER and LA opioids provide CE for prescribers
  - Safe prescribing practices for opioids
  - Risk reduction
- Providers who engage with REMS demonstrate safer prescribing habits

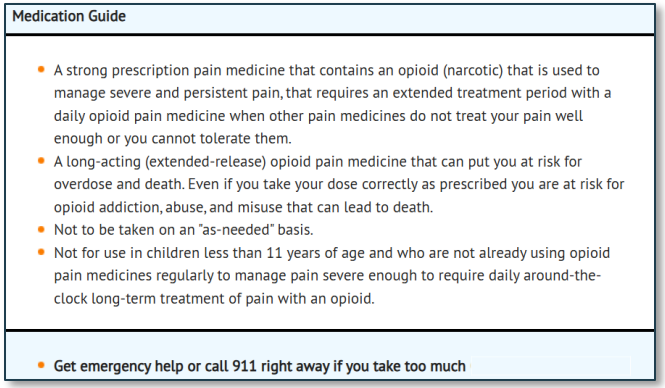
CE = continuing education; LA = long acting.

FDA. 2023. https://www.fda.gov/media/173774/download?attachment. Heyward J, et al. *JAMA Intern Med.* 2020;180(2):301-309. Cepeda MS, et al. *Pain Med.* 2017;18(1):78-85.

REMS Blueprint Overview

2. Patient Education

- Program requires that patients receive educational materials: medication guides, counseling forms
- Safe use, storage, and disposal of opioids
- Disposal 2024 update: manufacturers provide prepaid drug mail-back envelopes to pharmacies to facilitate safe opioid disposal for patients


Medication Guide

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain, that requires an extended treatment period with a daily opioid pain medicine when other pain medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not to be taken on an "as-needed" basis.
- Not for use in children less than 11 years of age and who are not already using opioid pain medicines regularly to manage pain severe enough to require daily around-the-clock long-term treatment of pain with an opioid.

- Get emergency help or call 911 right away if you take too much

FDA. 2023. https://www.fda.gov/media/173774/download?attachment.
FDA. 2024. https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know. FDA. https://dps.fda.gov/medguide.

REMS Blueprint Overview

3. Monitoring and Assessment

- The FDA requires manufacturers to conduct post-marketing studies and surveillance to assess effectiveness of REMS program in reducing adverse outcomes
  - Misuse, abuse, overdose, and death
  - Studies are ongoing, but methodological limitations

FDA. 2023. https://www.fda.gov/media/173774/download?attachment. Heyward J, et al. *JAMA Intern Med.* 2020;180(2):301-309.
Califf RM, et al. *N Engl J Med.* 2016;374(15):1480-1485.

REMS Blueprint Overview

4. Elements to Assure Safe Use (ETASU)

- Elements that include specific prescriber training, patient monitoring, restricted distribution systems
- Example: REMS for vigabatrin (anticonvulsant) includes ETASU to ensure providers are educated about the risk of permanent vision loss; counsel patients about the risk and conduct periodic ophthalmic monitoring

FDA. 2023. https://www.fda.gov/media/173774/download?attachment. Wu J, et al. *Clin Ther.* 2016;38(12):2526-2532.
Gassman AL, et al. *N Engl J Med.* 2017;376(7):674-682.

SMART Goals

- Prioritize non-opioid therapies as first-line treatment for pain when possible
- Develop patient-centered pain management plans that include setting goals for pain and function, discussing opioid risks and benefits, and prescribing the lowest effective dose of immediate-release opioids when needed
- Practice risk mitigation strategies, including naloxone co-prescribing, reviewing PDMP data, and avoiding concurrent opioid and benzodiazepine prescriptions